UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

CASE NO. 8:03-cv-1663-T-26MSS

v.

PHARMAKON LABORATORY, INC., a corporation; and ABELARDO L. ACEBO and EDWARD R. JACKSON, individuals,

Defendants.
_____/

ORDER OF PERMANENT INJUNCTION

The Court having found that Pharmakon Laboratory, Inc. (Pharmakon), its president Abelardo L. Acebo, and its secretary/treasurer, Edward R. Jackson (collectively referred to as Defendants), are making and distributing unapproved new drugs within the meaning of 21 U.S.C. §§ 321(p), 355(a), and adulterated drugs within the meaning of 21 U.S.C. § 351(a)(2)(B), and having found that Defendants are violating and, unless restrained by order of this Court, will continue to violate the Federal Food, Drug, and Cosmetic Act (the FDC Act), 21 U.S.C. §§ 331(a), (d) & (k),

IT IS HEREBY ORDERED AND ADJUDGED that:

1. This Court has jurisdiction over the subject matter and all parties to this action, and the complaint and amended complaint state a cause of action under the FDC Act, 21 U.S.C. §§ 301-397.

2. Defendants violate the FDC Act, 21 U.S.C. § 331(d), by introducing and causing to be introduced, and delivering and causing to be delivered for

introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

3. Defendants violate the FDC Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce drugs, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packaged, labeled, held, and distributed in violation of current good manufacturing practice (CGMP), 21 C.F.R. Parts 210 and 211, and 21 U.S.C. § 331(k), by causing the adulteration of said drugs while they are held for sale after shipment of one or more of their components in interstate commerce.

4. Defendants have violated the FDC Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded under 21 U.S.C. § 353(b)(4)(B), in that they are not prescription drugs within the meaning of 21 U.S.C. § 353(b)(1), but bear the "Rx only" symbol.

5. Defendants have violated the FDC Act, 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

6. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from

directly or indirectly doing or causing the manufacture, processing, packing, labeling, holding, or distribution of drugs, as defined by 21 U.S.C. § 321(g)(1), unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with CGMP. See 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendants' expense, an independent person or persons (the expert), without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their immediate families, who by reason of background, experience, education, and training, is qualified to inspect Defendants' drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify FDA in writing of the identity of the expert as soon as they retain such expert;

C. The expert shall perform a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs. The expert shall determine whether Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs are in compliance with CGMP;

D. The expert certifies in writing to FDA that: (1) he or she has inspected Defendants' facilities, processes, and controls; (2) all CGMP deviations brought to Defendants' attention by FDA and/or inspectors, trial testimony, or otherwise have been corrected; and (3) such facilities, processes, and controls are in compliance with the requirements of CGMP. As part of this certification, the expert shall include a full and complete detailed report of the results or his or her inspection;

E. Defendants report to FDA in writing the actions they have taken to: (1) correct the CGMP deviations brought to Defendants' attention by FDA and/or inspectors, trial testimony, or otherwise; and (2) ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and administered in conformity with CGMP;

F. FDA representatives inspect Defendants' facilities to determine whether the requirements of this Order have been met, and whether Defendants' facilities are otherwise operated in conformity with CGMP, the FDC Act, and its implementing regulations; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 6(A)-(E). 7.

Upon entry of this Order, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packing, labeling, holding, or distributing any drug identified in Appendix A, any product containing the same or similar ingredients as those identified in Appendix A, any product labeled as being similar in composition or effect to the drugs identified in Appendix A, or any other drug that is a new drug within the meaning of 21 U.S.C. § 321(p), unless and until:

(1) an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug;

(2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the investigational new drug application; or

(3) such drug product conforms strictly to all of the requirements set forth in any of the United States Food and Drug Administration (FDA) drug monographs, 21 C.F.R. Part 330.

B. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packing, labeling, holding, or distributing any misbranded drug, within the meaning of 21 U.S.C. § 353(b)(4)(B), or the misbranding of any drug within the meaning of 21 U.S.C. § 353(b)(4)(B), while such drug is held for sale after shipment of one or more components in interstate commerce.

8. Before Defendants may commence distributing a drug product identified in Appendix A, any product containing the same or similar ingredients as those identified in Appendix A, any product labeled as being similar in composition or effect to the drugs identified in Appendix A, or any new drug product, Defendants shall submit the drug's proposed labeling and package insert to FDA for review and shall demonstrate to FDA, as FDA deems appropriate, that the drug product strictly conforms to an FDA drug monograph, is the subject of an approved new drug application under 21 U.S.C. § 355(a), or is the subject of an investigational new drug application under 21 U.S.C. § 355(i). FDA will notify Defendants in writing within thirty (30) calendar days whether Defendants may commence commercial marketing of such drug.

9. Within fifteen (15) calendar days of entry of this Order, Defendants shall, under FDA supervision, destroy: (a) all of Pharmakon's drugs identified in Appendix A, any product containing the same or similar ingredients as those

identified in Appendix A, and any product labeled as being similar in composition or effect to the drugs identified in Appendix A in Defendants' possession, custody, and/or control; and (b) all other Pharmakon drugs products which are also adulterated because they were not manufactured, processed, packaged, labeled, held, and distributed in accordance with CGMP. Defendants shall not dispose of any drug products in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' places of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA representatives shall be permitted ready access to Defendants' places of business including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all of Defendants' drug products, including components, in order to ensure continuing compliance with the terms of this Order. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the FDC Act, 21 U.S.C. § 374. In addition, in order to ensure Defendants' compliance with this Order, Plaintiff and FDA are authorized to monitor Defendants' compliance with this Order by all lawful means, including but not limited to using representatives posing as consumers to contact Defendants' websites, employees, and representatives, and/or any other person or entity

managed or controlled in whole or in part by Defendants, without the necessity of identification or prior notice.

11. Within ten (10) calendar days of the entry of this Order, Defendants shall post a copy of this Order on a bulletin board in a common area at 6050 Jet Port Industrial Boulevard, Tampa, Florida, 6119 Jet Port Industrial Boulevard, Tampa, Florida, and at any other location at which Defendants conduct business, and shall ensure that the Order remains posted for a period of twelve (12) months at each location.

12. Within ten (10) calendar days of the date of entry of this Order, Defendants shall provide a copy of the Order, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (collectively referred to as Associated Persons). Within thirty (30) calendar days of the date of entry of this Order, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Order pursuant to this paragraph.

13. In the event that any of the Defendants becomes associated, at any time after entry of this Order, with any additional Associated Person(s), Defendants immediately shall provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time any of the Defendants becomes associated with any such additional Associated Person pursuant to this paragraph, and within ten (10) calendar days of doing so, Defendants shall provide to the District Director, FDA Florida District Office, an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all

Associated Persons who received a copy of this Order pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

14. Defendants shall notify the District Director, FDA Florida District Office, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of any of their businesses, including incorporation, reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, or any other change in the structure or identity of Pharmakon (or any of its divisions), or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Order. Defendants shall provide a copy of this Order to any prospective successor or assign at least ten (10) calendar days prior to any sale or assignment. Defendants shall furnish Plaintiff with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

15. After Defendants have complied with paragraphs 6(A)-(E) and FDA has notified them pursuant to paragraph 6(G), Defendants shall retain an independent person or persons who shall meet the criteria described in paragraph 6(B) (the auditor) to conduct audit inspections of their drug manufacturing operations not less than once every six (6) months for a period of no less than five (5) years. If Defendants choose, the auditor may be the same person or persons retained as the expert in paragraph 6(B).

A. At the conclusion of each audit inspection, the auditor shall prepare a written audit report (the audit report) analyzing whether Defendants are

in compliance with CGMP and identifying any deviations from CGMP (audit report observations). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspections are completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any audit report observations indicating that Defendants are not in compliance with CGMP, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, propose a schedule for completing corrections (correction schedule). That correction schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has

been corrected and, if not, which audit report observations remain uncorrected.

16. If, at any time after this Order has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data prepared or submitted by Defendants, the expert, the auditor, or any other information, that Defendants have failed to comply with any provision of this Order, or have violated CGMP, the FDC Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Order, CGMP, the FDC Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants to cease all manufacturing, processing, packing, labeling, holding, and/or distributing of any or all drug(s) and/or take any other corrective action FDA deems necessary to bring Defendants and their products into compliance with this Order, CGMP, the FDC Act, or its implementing regulations. In addition, Defendants shall, as and when FDA deems necessary, recall any drug(s) that are adulterated or misbranded or otherwise in violation of this Order, CGMP, the FDC Act, or its implementing regulations. Defendants shall bear all costs of such recall(s).

17. Any order issued pursuant to paragraph 16 shall issue from the District Director, FDA Florida District Office, and shall specify the deficiencies or violations giving rise to the order.

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving an order pursuant to paragraph 16, Defendants shall notify FDA in writing either that: (a) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or to be taken and the schedule for completing

the action; or (b) Defendants do not agree with FDA's order.

B. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and specific time frames for achieving FDA's objectives.

C. If Defendants advise FDA in writing that they do not agree with FDA's order, FDA will review Defendants' written material and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), or, if they so choose, bring the matter before this Court on an expedited basis.

18. Any cessation of operations described in paragraph 16 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, CGMP, the FDC Act, and its implementing regulations.

19. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Order shall be vested in FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A).

20. All notifications, correspondence, and communications to FDA required by the terms of this Order shall be addressed to the District Director, FDA Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

21. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Order and for the purpose of

granting such additional relief as may be necessary or appropriate, including the award of attorneys' fees, costs, and other expenses incurred by the United States in the implementaion of this order.

DONE AND ORDERED in Chambers at Tampa, Florida, this 21 day of July, 2005.

RICHARD A. LAZZARA
UNITED STATES DISTRICT JUDGE

Appendix A

Drug Name	Active Ingredients
GFN 800/DM 30 Tablets	Guaifenesin, 800 mg Dextromethorphan HBr, 30 mg
Mindal DM Tablets	Guaifenesin, 500 mg Dextromethorphan HBr, 30 mg
Allfen DM Tablets	Guaifenesin, 1000 mg Dextromethorphan HBr, 55 mg
AMBI 60/580/30 Tablets	Guaifenesin, 580 mg Dextromethorphan HBr, 30 mg Pseudoephedrine HCl, 60 mg
AMBI 80/700/40 Caplets	Guaifenesin, 700 mg Dextromethorphan HBr, 40 mg Pseudoephedrine HCl, 80 mg
AMBI 45/800/30 Caplets	Guaifenesin, 800 mg Dextromethorphan HBr, 30 mg Pseudoephedrine HCl, 45 mg
Ambifed-G DM Caplets	Guaifenesin, 1000 mg Dextromethorphan HBR, 30 mg Pseudoephedrine HCL, 60 mg
GeneBronco-D (liquid)	Guaifenesin, 400 mg/ 10 ml Dextromethorphan HBR, 40 mg/ 10 ml Pseudoephedrine HCl, 60 mg/ 10 ml
Maxiphen DM Caplets	Guaifenesin, 1000 mg Dextromethorphan HBr, 60 mg Phenylephrine HCl, 40 mg
GFN 1200/DM 20/PE 40 Tablets	Guaifenesin, 1200 mg Dextromethorphan HBr, 20 mg Phenylephrine HCl, 40 mg
AMBI 60/580 Tablets	Guaifenesin, 580 mg Pseudoephedrine HCl, 60 mg
AMBI 45/800 Caplets	Guaifenesin, 800 mg Pseudoephedrine HCl, 45 mg
AMBI 80/700 Caplets	Guaifenesin, 700 mg Pseudoephedrine HCl, 80 mg
GFN 800/PSE 60 Tablets	Guaifenesin, 800 mg Pseudoephedrine HCl, 60 mg
GFN 1200/PSE 50 Tablets	Guaifenesin, 1200 mg Pseudoephedrine HCl, 50 mg
Maxifed-G Tablets	Guaifenesin, 580 mg Pseudoephedrine HCl, 60 mg
Stamoist E Tablets	Guaifenesin, 500 mg Pseudoephedrine HCl, 120 mg
Ambifed-G Caplets	Guaifenesin, 1000 mg Pseudoephedrine HCl, 60 mg
GFN 800/PE 25 Tablets	Guaifenesin, 800 mg

	Phenylephrine HCl, 25 mg
Utira Tablets	Hyoscyamine Sulfate, 0.12mg Methenamine, 81.6 mg Phenyl Salicylate, 36.2 mg Sodium Biphosphate, 40.8 mg Methylene Blue, 10.8 mg
URIN D/S Tablets	Hyoscyamine Sulfate, 0.12 mg Methenamine, 81.6 mg Phenyl Salicylate, 36.2 mg Sodium Biphosphate, 40.8 mg Methylene Blue, 10.8 mg
Urogesic-Blue Tablets	Hyoscyamine Sulfate, 0.12 mg Methenamine, 81.6 mg Phenyl Salicylate, 36.2 mg Sodium Biphosphate, 40.8 mg Methylene Blue, 10.8 mg
Tannic-12 Tablets	Carbetapentane Tannate, 60 mg Chlorpheniramine Tannate, 5 mg
Allfen Tablets	Guaifenesin, 1000 mg Potassium Guaiacolsulfonate, 150 mg
Bellahist-D LA Tablets	Phenylephrine Hydrochloride, 20 mg Chlorpheniramine Maleate, 8 mg Atropine Sulfate, 0.04 mg Scopolamine Hydrobromide, 0.01 mg Hyoscyamine Sulfate, 0.19 mg
ED-Chlor-Tan Tablets	Chlorpheniramine Tannate, 8 mg
ED-A-Hist DM (liquid)	Chlorpheniramine Maleate, 4 mg/ 5 ml Phenylephrine HCl, 10 mg/ 5 ml Dextromethorphan HBr, 15 mg/ 5 ml
ED-A-Hist Caplets	Chlorpheniramine Maleate, 8 mg Phenylephrine HCl, 20 mg
ED A-Hist (liquid)	Chlorpheniramine Maleate, 4 mg/ 5 ml Phenylephrine HCl, 10 mg/ 5 ml Alcohol, 5%/ 5 ml
Poly-Tussin XP (liquid)	Hydrocodone Bitartrate, 5 mg/5 ml Guaifenesin, 200 mg/5 ml Pseudoephedrine HCl, 60 mg/5 ml
AMBI 5/15/100 (liquid)	Hydrocodone Bitartrate, 5 mg/5 ml Guaifenesin, 100 mg/5 ml Phenylephrine HCl, 15 mg/5 ml
Maxi-Tuss HCG (liquid)	Hydrocodone Bitartrate, 6 mg/5 ml Guaifenesin, 200 mg/5 ml
Maxi-Tuss HCX (liquid)	Hydrocodone Bitartrate, 6 mg/5 ml Chlorpheniramine Maleate, 2 mg/5 ml Phenylephrine HCL, 12 mg/5 ml
Maxi-Tuss HC (liquid)	Hydrocodone Bitartrate, 2.5 mg/5 ml Chlorpheniramine Maleate, 4 mg/5 ml

	Phenylephrine HCl, 10 mg/5 ml
Jaycof-HC (liquid)	Hydrocodone Bitartrate, 3 mg/5 ml Chlorpheniramine Maleate, 2 mg/5 ml Pseudoephedrine HCl, 15 mg/5 ml
Ztuss Expectorant (liquid)	Hydrocodone Bitartrate, 2.5 mg/5 ml Pseudoephedrine HCl, 15 mg/5 ml Chlorpheniramine Maleate, 2 mg/5 ml Guaifenesin, 100 mg/5 ml
Jaycof Expectorant (liquid)	Hydrocodone Bitartrate, 5 mg/5 ml Potassium Guaiacolsulfonate, 300 mg/5 ml
Poly-Tussin HD (liquid)	Hydrocodone Bitartrate, 6 mg/5 ml Chlorpheniramine Maleate, 2 mg/5 ml Phenylephrine HCl, 5 mg/5 ml
Poly-Tussin Syrup (liquid)	Hydrocodone Bitartrate, 5 mg/5 ml Chlorpheniramine Maleate, 2 mg/5 ml Phenylephrine HCl, 5 mg/5 ml
ED-Bron G (liquid)	Theophylline, 150 mg/15 ml Guaifenesin, 100 mg/15 ml
Tusnel Ped-C (liquid)	Codeine Phosphate, 5 mg/5 cc Guaifenesin, 50 mg/5 cc Pseudoephedrine HCl, 15 mg/5 cc
Tusnel-HC (liquid)	Hydrocodone Bitartrate, 5 mg/5 ml Guaifenesin, 200 mg/5 ml Brompheniramine Maleate, 2 mg/5 ml